K011795

JUN 1 3 2001

BIOMET

CORPORATE HEADQUARTERS

SUMMARY OF SAFETY AND EFFECTIVENESS

Sponsor: Biomet Orthopedics, Inc.
P.O. Box 587
Warsaw, IN 46581-0587

Contact Person: Tracy J. Bickel
(219) 267-6639

Proprietary Name: Worland Unicondylar Tibial Bearing

Common Name: Unicompartmental Knee Tibial Component

Classification Name: Prosthesis, Knee, Femorotibial, semi-constrained, cemented, metal/polymer (21 CFR 888.350)

Substantially Equivalent Devices: Repicci II™ Unicondylar All Poly Tibial Bearing – K980665

Device Description: The Repicci II™ Unicondylar Knee System consists of a femoral and tibial component. The Worland tibial bearing is used with the Repicci II™ femoral components (K971938).

The all polyethylene tibial components are anatomical in geometry with right and left medial/lateral allocations. Located on the inferior surface of the implant is a patterned face with holes and a fin.

Intended Use: Partial replacement of articulating surfaces of the knee when only one side of the joint is affected due to compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous arthroplasty.

The devices covered in this 510(k) are intended to be used with Repicci™ Femoral Components.

The device is a single use implant intended for implantation w/ bone cement.

Summary of Technologies: The Worland Unicondylar Tibial components materials, design, sizing, and indications are similar to or identical to the predicate devices.

Non-Clinical Testing: Fatigue testing and stress analysis determined that the Worland Unicondylar Tibular components presented no new risks and were; therefore, substantially equivalent to the predicate device.

Clinical Testing: None provided as a basis for substantial equivalence.

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE
219.267.6639

FAX
219.267.8137

E-MAIL
biomet@biomet.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 13 2001

Ms. Tracy Bickel
Regulatory Specialist
Biomet, Inc
56 Bell Drive
Warsaw, Indiana 46582

Re: K011795
Trade Name: Worland Unicondylar Tibial Bearing
Regulation Number: 888.3560
Regulatory Class: II
Product Code: HRY
Dated: June 7, 2001
Received: June 8, 2001

Dear Ms. Bickel:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011795
Device Name: **Worland Unicondylar Tibial Bearings**
Indications for Use:

Partial replacement of articulating surfaces of the knee when only one side of the joint is affected due to compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous arthroplasty.

The devices covered in this 510(k) are intended to be used with Repicci™ Femoral Components.

The device is a single use implant intended for implantation with bone cement.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K011795

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)